

REMARKS

The Examiner has rejected the elected claims under 35 U.S.C. 103(a) as unpatentable over Sundstrom et al (U.S. 6,388,056 B1).

First of all, the present invention relates to the use of isoleucine and active isomers and analogs of isoleucine (see page 2, lines 20-page 3, lines 3), and the term "isoleucine" as used in the claims includes but is limited to the above. There are no polypeptides or even additional single amino acids that are included in the term "isoleucine".

Sundstrom's patent is directed to a long chain polypeptide (40-187 amino acids- see Fig. 1) containing isoleucine among a large number of other amino acids, all of which are set forth in a set fixed sequence in the polypeptide chain. This is the required polypeptide (or an antigenic portion thereof) that is necessary for the purposes of Sundstrom's invention.

There is no disclosure in Sundstrom of isoleucine itself.

Secondly, the present invention is based on the discovery that isoleucine blocks microbial adherence to eukaryotic cell surfaces.

Sundstrom's polypeptide functions by a different mechanism, namely, "the prevention and treatment of microbial infection of a mammalian host through the administration of substrates for transglutaminases or antibodies against such substrates that inhibit the transglutaminase-mediated interaction of the microorganism with the mammalian host." (See col. 3, lines 43-49).

On page 4 of the action, the Examiner refers to column 8, lines 34-52 of the Sundstrom reference. The Examiner's discussion of Sundstrom's teaching here is believed to be correct. However, there is no teaching here of isoleucine itself or any

teaching that isoleucine can function to block microbial adherence to the surfaces of eukaryotic cells.

The only teaching by Sundstrom is with respect to the adherence of microbes to host cell surfaces, but not even a teaching that the polypeptide can block such adherence by microbes, only that the polypeptide can act as a substrate for mammalian transglutaminases to inhibit binding of the transglutaminase to purified Hwp1 protein.

As set forth in column 1, lines 46-58, the Hwp 1 protein is a hyphal wall protein expressed on hyphal surfaces of the pathogenic fungus Candida albicans. As stated on lines 51-58 "Hwp 1 consists of N-terminal proline and glutamine-rich repetitive amino acid sequence that is exposed on the hyphal surface, and a cell wall-anchored serine and threonine-rich C-terminus. The composition of the N-terminal amino acid repeats is reminiscent of mammalian transglutaminase substrates. It is now known that Hwp 1 can serve as a substrate in transglutaminase-mediated cross-linking reactions".

The above disclosure and use of the Hwp 1 fungus protein has nothing whatsoever to do with the present invention.

On page 5 of the Office Action, the Examiner contends that "the prior art teaches the generic concept of the use of isoleucine to inhibit microbial infection and interaction with the mammalian host, since isoleucine is within the group of polypeptides disclosed at columns 10 and 16. One of ordinary skill would recognize that since isoleucine is taught to inhibit microbial interaction, it also teaches the prevention of the adherence of microbes, as desired by the applicant. Hence, no significant distinction is observed between the prior art and the instant invention."

The Examiner's contentions are respectfully controverted. It is not agreed that the prior art teaches the use of isoleucine to inhibit microbial infection and interaction with the mammalian host since only a long chain polypeptide was found to have this function.

Moreover, the use of isoleucine acts as an adhesion inhibitor for pathogenic organisms, and not as a substrate for transglutaminases which is the function of Sundstrom's polypeptide.

In addition, isoleucine is not taught to inhibit microbial interaction as contended by the Examiner since Sundstrom contains no disclosure of isoleucine itself or the present discovery that isoleucine blocks microbial adherence to cell surfaces.

The Examiner also contends that the claimed amounts and ranges of isoleucine are obvious by the use of experimentation. However, since isoleucine itself is not disclosed by Sandstrom, this contention is respectfully submitted to be incorrect.

With respect to the above arguments, the Examiner is undoubtedly aware that it is improper to rebuild a reference, in light of applicant's disclosure, in order for it to operate in a manner never intended or contemplated by the reference. Ex part Garrett, POBA (1961) 132 USPQ 514. The reference, viewed by itself and not in retrospect, must suggest doing what applicant has done. In re Schaffer (CCPA 1956) 108 USPQ 326, In re Skoll (CCPA 1975) 187 USPQ 481.

Accordingly, allowance of claims 1-16, 18, 25, 31, 32 and 34 is respectfully solicited, as well as non-elected claims 17, 19-24, 26-30, 33, and 35-40.

Respectfully submitted,



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